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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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William R. Jacobs JR.

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11/05/2009

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

11/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,958	Applicant(s) JACOBS ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,8,10,19,41 and 87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,8,10,19,41 and 87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/14/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 July 2009 has been entered.

Claims 1 and 19 have been amended. Claims 12, 13, 16-18, 22-25, 28, 30, 32, 38 and 39 have been cancelled.

2. It is noted that claim 19 is improperly designated as (Original), but is amended. In order to expedite the application prosecution, the examiner is entering the amendment. However, future designation of claim 19 should be (Previously Presented).

3. Claims 1, 5, 8, 10, 19, 41 and 87 are pending and under consideration.

Rejections Moot or Withdrawn

4. The rejection of claims 12, 13, 16-18, 22-25, 28, 30, 32, 38 and 39 under 35 U.S.C. 112, first paragraph, scope of enablement for inoculation of mammals against all species of mycobacteria in the *M. tuberculosis* complex, is moot in light of the cancellation of the claims.

5. The rejection of claims 12, 13, 16-18, 22-25, 28, 30, 32, 38 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for "a" *M. tuberculosis* complex, is moot in light of the cancellation of the claims.

6. The rejection of claims 1, 5, 8, 10, 19, 41 and 87 under 35 U.S.C. 112, first paragraph, scope of enablement for inoculation of mammals against all species of mycobacteria in the *M. tuberculosis* complex, is withdrawn in light of the amendment of the claims.

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7. The rejection of claims 1, 5, 8, 10, 19, 41 and 87 under 35 U.S.C. 112, second paragraph, as being indefinite for "a" *M. tuberculosis* complex, is withdrawn in light of the amendment of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 5, 8, 10, 19, 41 and 87 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inoculating a mouse against *M. tuberculosis* utilizing an attenuated *M. tuberculosis* or *M. bovis* which has a deletion of RD1 and is auxotrophic for pantothenate, does not reasonably provide enablement for a method for inoculating all mammals against *M. tuberculosis* utilizing an attenuated *M. tuberculosis* or *M. bovis* which has a deletion of RD1 and is auxotrophic for pantothenate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims in light of Waters et al (*Vaccine*, Vol 25, pages 7832-7840, 2007).

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

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The nature of the invention - a method for inoculating a mammal against *M. tuberculosis* utilizing an attenuated *M. tuberculosis* or *M. bovis* which has a deletion of RD1 and is auxotrophic for pantothenate

The state of the art as evidenced by a post-filing reference which utilizes the same attenuated *M. tuberculosis* construct, mc²6030, which has a double deletion mutation, i.e., $\Delta RD1 \Delta panCD$, indicates that "vaccination trials with mc²6030 failed to protect cynomolgus monkeys from virulent *M. tuberculosis*"; (page 7838, first paragraph of section **4. Discussion**). Thus, there is a lack of predictability in the art that the claimed double mutant inoculates all mammals against *M. tuberculosis*.

The amount of direction/guidance/working examples in the instant specification is insufficient support for the broad scope of the instant claims. The only example of an attenuated *M. tuberculosis* or *M. bovis* which has a deletion of RD1 and is auxotrophic for pantothenate, mc²6030, Ex. 6 and 7, utilizes mice as the mammal. As stated *supra*, Waters et al., utilize the same construct, mc²6030, and found that mc²6030 failed to protect cynomolgus monkeys from virulent *M. tuberculosis*.

Thus, success in one mammal species, i.e., mice, and failure in one other mammal species, i.e., monkeys, is insufficient support for the scope of the instant claims, i.e., the method would be successful in any other mammal species besides mice.

The quantity of experimentation necessary to provide sufficient support for the instant claims in light of one success and one failure, constitute merely an invitation to experiment with all mammals without a reasonable expectation of success.

Conclusion

9. No claims are allowed.

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10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

November 5, 2009